jc618 U.S. PTO
11/30/98

DIVISIONAL-CONTINUATION APPLICATION TRANSMITTAL FORM UNDER RULE 1.53(b) (former Rule 1.60)

DOCKET NUMBER	ANTICIPATED CLASSIFICATION OF THIS APPLICATION:		PRIOR APPLICATION SERIAL NUMBER:	PRIOR APPLICATION FILING DATE:
ROE-040C5	CLASS:	SUBCLASS:	EXAMINER: D. SHAY	ART UNIT: 3311

ASSISTANT COMMISSIONER FOR PATENTS
BOX PATENT APPLICATION
WASHINGTON, DC 20231

CERTIFICATION UNDER 37 CFR 1.10

Date of Deposit:November 30, 1998 Mailing Label Number:EI288736036US

I hereby certify that this 37 CFR 1.53(b) request and the documents referred to as attached therein are being deposited with the United States Postal Service on the date indicated above in an envelope as "Express Mail Post Office to Addressee" service under 37 CFR 1.10 and addressed to the Assistant Commissioner for Patents, Box Patent Application, Washington, D.C. 20231.

THOMAS J. ENGELLENER
Name of Person Mailing Paper

Signature of Person Mailing Paper

jc549 U.S. PTO
09/201072
11/30/98

09201072 113098

Dear Sir:

This is a request for filing a ☒ continuation ☐ divisional application under 37 CFR 1.53(b), of pending prior application serial no. 08/411,581, filed 03/29/95, which is a continuation of 08/049,147, filed 04/19/93, which is a divisional of 07/568,348, filed 08/15/90, which is a continuation of 07/257,760, filed 10/14/88, which is a continuation of 07/014,990, filed 02/17/87, which is a continuation 06/761,188, filed 07/31/85, entitled INFRARED LASER CATHETER SYSTEM.

1. ☒ Enclosed is a copy of the latest inventor signed application, including the oath or declaration as originally filed. The copy of the enclosed papers is as follows:
   - ☒ 21 page(s) of specification
   - ☒ 11 page(s) of claims
   - ☒ 1 page of abstract
   - ☒6 sheet(s) of drawing
   - ☒1 page of declaration and power of attorney.

   I hereby verify that the attached papers are a true copy of the prior complete application serial no. 08/411,581 as originally filed on March 29, 1995.
2. ☐ A verified statement to establish small entity status under 37 CFR 1.9 and 1.27, a copy of which is enclosed, was filed in the prior application and such status is still proper and desired (37 CFR 1.28(a)).
3. ☒ The filing fee is calculated below:

	NUMBER OF CLAIMS FILED			NUMBER EXTRA
TOTAL	* 1	MINUS	** 20	=0
INDEP.	* 1	MINUS	*** 3	=0
☐ MULTIPLE DEPENDENT CLAIMS				

SMALL ENTITY			OTHER THAN A SMALL ENTITY	
RATE	FEE	OR	RATE	FEE
x 11 =	$.00		x 18 =	$.00
x 41 =	$.00		x 78 =	$.00
+135 =	$.00		+ 260 =	$.00
BASIC FEE	$.00		BASIC FEE	$760.00
TOTAL	0	OR	TOTAL	$760.00

4. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 14-1449. A duplicate copy of this sheet is enclosed.

5. ☒ A check in the amount of $760.00 is enclosed for payment of the filing fee.

6. ☒ Cancel in this application original claims 2-43 of the prior application before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)

7. ☐ A preliminary amendment **will be filed shortly**. (Claims added by this amendment have been properly numbered consecutively beginning with the number next following the highest numbered original claims in the prior application.)

8. ☒ Amend the specification by inserting before the first line the sentences: "This application is a continuation of application serial no. 08/411,581, filed 03/29/95, which is a continuation of 08/049,147, filed 04/19/93, which is a divisional of 07/568,348, filed 08/15/90, which is a continuation of 07/257,760, filed 10/14/88, which is a continuation of 07/014,990, filed 02/17/87, which is a continuation 06/761,188, filed 07/31/85. The contents of all of the aforementioned application(s) are hereby incorporated by reference."

9. ☐ Please abandon said prior application as of the filing date accorded this application. A duplicate copy of this transmittal is enclosed for filing in the prior application file. (May be used if signed by person authorized by §1.138 and before payment of base issue fee.)

10. ☒Letter to the Official Draftsman enclosing FIGS. 6, 7, 8, 9, 10, 11 and 11A-11C.

11. ☐ Priority of application serial no._____ filed on _____ in _____ is claimed under 35 U.S.C. §119.
    - ☐ The certified copy has been filed in prior application serial no. _____ filed on _____.
    - ☐ The certified copy will follow.

12. ☒ Revocation of Prior Powers of Attorney and Appointment of New Power of Attorney.

13. ### A _____ month extension of time has been submitted in the parent application Serial No. in order to establish copendency with the present application.

14. ### Also enclosed is/are .

15. ### The power of attorney in the prior application is to _____.

    a. ### The power appears in the original papers in the prior application.

    b. ☒ Since the power does not appear in the original papers, a copy of the power in the prior application is enclosed.

    c. ☐ A new power has been executed and is attached.

16. ☒ Address all future communications (May only be completed by applicant, or attorney or agent of record) to Thomas J. Engellenner, Esq. whose address is:

    Nutter, McClennen & Fish, LLP
    One International Place
    Boston, Massachusetts 02110

17. ☒ Any requests for extensions of time necessary in a parent application for establishing copendency between this application and a parent application are hereby requested and the Commissioner is authorized to charge any fee associated with such an extension to Deposit Account No. 14-1449.

18. ☐ Pursuant to 37 CFR 1.821(e), the computer readable form of the sequence listing for this new application is to be identical with the computer readable form of application serial no._____. Please use the computer readable form of application serial no._____ in lieu of filing a duplicate computer readable form in this application. Pursuant to 37 CFR 1.821(f), the content of the paper copy of the sequence listing for this new application and the computer readable form of application serial no._____ are the same.

November 30, 1998
Date

Thomas J. Engellenner
Reg. No. 28,711
☐ inventor(s) ☐ filed under §1.34(a)
☐ assignee of complete interest
☒ attorney or agent of record

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09021-27/0120260

INFRARED LASER CATHETER SYSTEM

Field of the Invention

This invention relates to laser catheters and optical fiber systems for generating and transmitting energy to a surgical site in a living body for the purposes of tissue removal or repair.

Background of the Invention

While lasers have been used for many years for industrial purposes such as drilling and cutting materials, it is only recently that surgeons have begin to use lasers for surgical operations on living tissue. To this end, laser energy has been used to repair retinal tissue and to cauterize blood vessels in the stomach and colon.

In many surgical situations, it is desirable to transmit laser energy down an optical fiber to the surgical location. If this can be done, the optical fiber can be included in a catheter which can be inserted into the body through a small opening, thus reducing the surgical trauma associated with the operation. In addition, the catheter can often be maneuvered to surgical sites which are so restricted that conventional scalpel surgery is difficult, if not impossible. For example, laser energy can be used to remove atherosclerotic plaque from the walls of the vasculature and to repair defects in small-diameter artery walls.

A problem has been encountered with laser surgery in that prior art lasers which have been used for industrial purposes often have characteristics which are not well suited to percutaneous laser surgery. For example, a laser which is conventionally used for scientific purposes is an excimer laser which is a gas laser that operates with a gas mixture such as Argon-Fluorine, Krypton-Fluorine or Xenon-Fluorine. Another common industrial laser is the carbon dioxide or CO_2 laser.

Both the excimer laser and the CO_2 laser have been used for surgical purposes with varying results. One problem with excimer lasers is that they produce output energy having a wavelength in the range 0.2-0.5 micrometers. Blood hemoglobin and proteins have a relatively high absorption of energy in this wavelength range and, thus, the output beam of an excimer laser has a very short absorption length in these materials (the absorption length is the distance in the materials over which the laser beam can travel before most of the energy is absorbed). Consequently, the surgical site in which these lasers are to be used must be cleared of blood prior to the operation, otherwise most of the laser energy will be absorbed by intervening blood before it reaches the surgical area. While the removal of blood is possible if surgery is performed on an open area it is often difficult if surgery is to be performed via a catheter located in an artery or vein.

An additional problem with excimer lasers is that the output energy pulse developed by the laser is very short, typically about ten nanoseconds. In order to develop reasonable average power, pulses with extremely high peak power must be used. When an attempt is made to channel such a high peak power output into an optical fiber, the high peak power destroys the fiber. Thus, excimer lasers have a practical power limit which is relatively low. Consequently, when these lasers are used for biological tissue removal, the operation is slow and time consuming.

The CO_2 laser has other drawbacks. This laser generates output energy with a wavelength on the order of 10 micrometers. At this wavelength, the absorption of blood hemoglobin is negligible but the absorption by water and tissue is relatively high. Scattering at this wavelength is also very low. Although the CO_2 laser possesses favorable characteristics for surgical applications in that it has low scattering and high absorption in tissue, it suffers from the same drawback as excimer lasers in that the absorption length is relatively short due to the high absorption of the laser energy in water. Thus, the surgical area must be cleared of blood prior to the operation.

Unfortunately, the CO_2 laser also suffers from a serious additional problem. Due to the long wavelength, the output energy from the carbon dioxide laser cannot be presently transmitted down any optical fibers which are

suitable for use in percutaneous surgery (present fibers which can transmit energy from a CO_2 laser are either composed of toxic materials, are soluble in water or are not readily bendable, or possess a combination of the previous problems) and, thus, the laser is only suitable for operations in which the laser energy can be either applied directly to the surgical area or applied by means of an optical system comprised of prisms or mirrors.

Accordingly, it is an object of the present invention to provide a laser catheter system which uses laser energy of a wavelength that is strongly absorbed in water, in bodily tissues and atherosclerotic plaque.

It is another object of the present invention to provide a laser catheter system which is capable of providing laser energy that can be transmitted through existing silica-based optical fibers.

It is a further object of the present invention to provide a laser catheter system in which optical scattering is minimized and which has a medium-length absorption length to confine the energy to the area of interest.

It is yet another object of the present invention to provide an optical catheter system with a laser that can be operated on either a pulsed mode or a continuous wave mode.

It is still another object of the present invention to provide a laser catheter system which can be used for biological material removal and biological material repair.

Summary of the Invention

The foregoing objects are achieved and the foregoing problems are solved in one illustrative embodiment of the invention in which a laser catheter system employs a laser source operating in the wavelength region of 1.4-2.2 micrometers. Illustrative laser sources operating this region are Holmium-doped YAG, Holmium-doped YLF, Erbium-doped YAG, Erbium-doped YLF and Thulium-doped YAG lasers.

In the inventive laser system, the above-noted lasers are used with a specially-treated silica fiber that has been purified to reduce the concentration of hydroxyl (OH-) ions.

For biological tissue removal, the laser source may be operated in a pulsed mode with a relatively long pulse of approximately 0.2-5 milliseconds at an energy level of approximately 1-2 joules per pulse. With this time duration and energy level, the peak power of the laser pulse is approximately 1 kilowatt. This amount of power can easily be tolerated by the silica fiber, but is sufficient for rapid material removal. With a repetition rate in the range of 1-10 hertz, the average power delivered to a surgical site by such a laser will be under 10 watts.

Alternatively, for biological tissue repair, the laser source can be operated in a low power continuous wave mode to repair, by coagulation, of tissue by a process similar to "spot welding".

Brief Description of the Drawing

Figure 1 shows a sketch of absorption of electromagnetic energy versus wavelength and electromagnetic energy scattering versus wavelength.

Figure 2 shows an absorption versus wavelength plot for atherosclerotic plaque obtained in a carotid endarterectomy with the region of interest for the inventive laser sources (1.4-2.2 micrometers) outlined.

Figure 3 of the drawing is a schematic diagram of a typical solid state laser construction used in the inventive laser sources.

Figure 4 of the drawing is a plot of laser output intensity versus time for a typical pulse shape developed by a laser shown in Figure 3 when used for tissue removal.

Figure 5 is a schematic diagram of a laser catheter which employs a single optical fiber for transmitting laser energy to a surgical location.

Figure 6 of the drawing is an enlarged cross-section of the probe tip the single fiber catheter shown in Figure 5.

Figure 7 is a schematic diagram of a wire-guided catheter which employs four optical fibers to increase the area which can be irradiated with the laser light.

Figure 8 of the drawing is an enlarged cross-sectional view of the probe tip of the catheter shown in Figure 7 showing the four optical fibers.

Figure 9 of the drawing is a schematic diagram of the beam pattern produced by the four-fiber catheter at the surgical location.

Detailed Description of the Preferred Embodiment

The absorption and scattering characteristics versus output wavelength of a plurality of known laser systems are shown in Figure 1. Figure 1 has a logarithmic scale representing the absorption coefficient in units of cm^{-1} along the vertical axis and the incident energy wavelength in micrometers along the horizontal axis.

From Figure 1, it can be seen that excimer laser systems which utilize conventional gas mixtures, such as Argon-Fluorine, Krypton-Fluorine and Xenon-Fluorine, and Argon gas lasers produce output energy which falls in the 0.2-0.5 micrometer wavelength region. In this region, the absorption of blood hemoglobin and proteins is very high. Consequently, the absorption length is very short (about 5-10 microns) and virtually no blood can be present between the fiber end and the surgical site during the operation. Thus, it is necessary to remove blood from the surgical area when these lasers are used for surgical purposes.

In addition, for lasers such as Argon, the absorption of water reaches a minimum at 0.5 micrometers so that it is necessary to use a higher power laser than is desirable to achieve sufficient power in the surgical area for material

cutting and removal. Also, due to the low absorption of the laser output in water and hemoglobin, the absorption length is very long (approximately 1 mm). In addition, scattering for these lasers is relatively high, causing difficulty in controlling the laser energy and a danger of tissue damage outside the surgical area due to scattering of the laser energy.

At the other end of the wavelength spectrum shown in Figure 1 are carbon monoxide and carbon dioxide lasers producing outputs at 5 and 10 micrometers, respectively. At these wavelengths scattering is negligible and absorption by water and tissue is relatively high and thus both lasers have good surgical properties. Unfortunately, due to the high absorption of water, the absorption length is relatively short (about 20 microns). Further, silica-based optical fibers in present use which are suitable for percutaneous surgical use have a practical "cutoff" in transmission which occurs approximately at 2.3 micrometers, and, thus, the output energy from carbon monoxide and carbon dioxide lasers cannot be transmitted through such an optical fiber.

In accordance with the invention, laser sources of interest are those that lie in the wavelength range of approximately 1.4-2.15 micrometers. As shown in Figure 1, in this range, the energy absorption of water is relatively high whereas optical scattering is relatively low. Illustrative lasers which are useful with the present invention comprise

Erbium-doped Yttrium Aluminum Garnet (YAG) with a wavelength of 1.55 micrometers, Erbium-doped Yttrium Lithium Fluoride (YLF) with a wavelength of 1.73 micrometers, Thulium-doped YAG with a wavelength of 1.88 micrometers, Holmium YLF with a wavelength of 2.06 micrometers and Holmium YAG at a wavelength of 2.1 micrometers. The absorption of the laser energy produced by lasers in this latter group by water is moderately high and, consequently, the absorption by biological tissues of such energy will also be relatively high. However, the absorption by water is not as high as the absorption of CO and CO_2 laser energy. Thus, the absorption length will be longer for the lasers operating in the 1.4-2.2 micron range. Typically, the absorption length in the body for these latter lasers is about 200 microns. Therefore, it is still possible to operate satisfactorily even with 10-30 microns of blood between the fiber end and the surgical site.

Of particular interest is the absorption of the laser energy by atherosclerotic plaque, since an important use of laser catheter systems is angioplasty, particularly the clearing of blocked arteries. Figure 2 is a plot of the absorption by plaque of electromagnetic energy versus wavelength for energy in the wavelength range of 0.2-2.2 micrometers. As shown in Figure 2, the absorption by plaque of electromagnetic energy reaches a minimum in the 0.8-1 micrometer wavelength range and generally increases with increasing wavelength in the wavelength region of 1-2.2 micrometers.

In the wavelength range from 1.4-2.2 micrometers, the wavelength range produced by laser in the above-mentioned group, the absorption by plaque is at a relatively high value.

A schematic diagram of a typical solid-state laser construction is shown in Figure 3. The laser assembly consists of a laser crystal 1 and an excitation device such as a flashlamp 3. Typically, for the crystal compositions disclosed above, the laser crystal must be cooled to cryogenic temperature to provide low laser-threshhold operation. Cryogenic cooling is typically provided by enclosing crystal 1 in a quartz or fused-silica jacket 4 through which liquid nitrogen is circulated. Liquid nitrogen enters jacket 4 by means of an inlet pipe 5 and leaves by means of an outlet pipe 6. The laser cavity is formed by a high-reflectivity concave mirror 10 and a partial reflector 12.

Generally, the crystal is excited by optical pumping which is, in turn, accomplished by irradiating the crystal with light from a flashlamp 3. A flashlamp which is typically used with the inventive laser compositions is a high-pressure Xenon flashlamp. Lamp 3 may also be surrounded by a quartz flow tube (not shown) through which coolant is pumped.

Crystal 1 and flashlamp 3 are enclosed in a reflector 2 which concentrates the flashlamp energy into the laser crystal. To maximize energy transfer from lamp 3 to crystal

1, the inner surface of reflector 2 is coated with a material chosen to have high-reflectivity at the pumping wavelength of the laser crystal - illustratively, aluminum or silver. In order to provide thermal insulation to prevent condensation on the system optics, it may be necessary to evacuate the interior of reflector 2 or to provide a vacuum jacket around crystal 1.

The construction of cryogenic solid-state lasers is conventional and described in a variety of sources; accordingly such construction will not be discussed further in detail herein. A more complete discussion of construction details of a typical cryogenic laser is set forth in an article entitled "TEM_{oo} Mode Ho:YLF laser", N.P. Barnes, D.J. Gettemy, N.J. Levinos and J.E. Griggs, Society of Photo-Optical Instrumentation Engineers, Volume 190 - LASL Conference on Optics 1979, pp 297-304.

Figure 4 of the drawing is a plot of the illustrative pulse shape developed by a laser in the preferred group when used in the "material removal" mode. Figure 4 shows light intensity along the vertical axis increasing in the downward direction versus time increasing towards the right. Although, as shown in Figure 4, the laser source has been adjusted to produce an output pulse of relatively long time duration, most of the output energy is released within approximately 1 millisecond of the beginning of the pulse. It should also be noted,as illustrated in Figure 4, that

lasers in the preferred laser group exhibit a "spiking" phenomenon caused by internal relaxation-oscillations in the laser crystal. The spiking behavior causes local increases in laser intensity which have a large magnitude, but a very short time duration. Similar "spiking" behavior has been found advantageous when lasers are used to drill metals and other materials for industrial purposes and it is believed that such "spiking" behavior enhances the laser usefulness for biological material removal.

Figure 5 is a schematic diagram of a laser/catheter system employing a solid state laser of the type shown in detail in Figure 3. More specifically, the infrared output energy of laser 21 is focused by a conventional focusing lens onto the end of the optical fiber which is held in a conventional fiber optic connector 24. Fiber optic connector 24 is, in turn, connected to a tube 27 which houses a single optical fiber. Tube 27 is connected to a conventional two-lumen catheter 30 by means of a bifurcation fitting 28.

Illustratively, catheter 30 has two lumens passing axially therethrough to its distal end 34 so that an optical fiber can pass through one lumen and transmit laser energy from fiber optic connector 24 to lens tip 34. As previously mentioned, the optical fiber which passes through the catheter is specially purified to reduce the hydroxyl ion concentration to a low level, thus preventing the laser energy which is transmitted down the fiber from being highly

absorbed in the fiber material. A fiber which is suitable for use with the illustrative embodiment is a fused-silica optical fiber part no. 822W manufactured by the Spectran Corporation located in Sturbridge, Massachusetts.

Advantageously, the mirrors and lenses (10, 12 and 22) which are used to form the IR laser cavity and focus the output energy beam are generally only reflective to energy with a wavelength falling within a narrow wavelength band and transparent to energy at other wavelengths. Consequently, the mirrors and lenses are transparent to visible light. An aiming laser 20 (for example, a conventional helium-neon laser) which generates visible light may be placed in series with IR laser 21 to generate a visible light beam. This light beam may be used to align mirrors 10 and 12 and to adjust focussing lens 22 so that the optical fiber system can be aligned prior to performing surgery.

Also, the optical fibers used to transmit the IR energy from laser 21 to the surgical area can also be used to transmit the visible light from the aiming laser 20 to the surgical area. Thus, when the inventive system is used in performing surgery where the surgical area is visible to the surgeon, the light produced by laser 20 passes through the optical fiber in catheter 30 and can be used to aim the probe tip before laser 21 is turned on to perform the actual operation.

The second lumen in catheter 30 is provided for transmission of a flushing fluid or to apply suction to the probe lens tip area to clear the area of blood during surgery. This latter lumen is connected through bifurcation fitting 28 to a second tube 29. Tube 29 may illustratively be terminated by a standard Luer-Lok fitting 26 which allows connection of the catheter to injectors and standard flow fittings. Solutions injected into the catheter through tube 29 pass through the lumen in catheter 30 and exit at the distal end via a small orifice 32.

Probe tip 34 consists of a lens arrangement which forms the laser energy into a beam 36 which is used to perform the surgical operations. An enlarged view of the probe tip is shown in Figures 6 and 7.

To ensure that the distal end of optical fiber 18 is spaced and oriented in a precise position with respect to the end of the probe, fiber 18 is mounted in a high-precision holder 58 which has a reduced diameter end 64 that forms a shoulder 68. Shoulder 68, as will hereinafter be described, is used to hold the probe tip assembly together. Holder 58 has a precision-formed axial bore made up of two sections, including a large-diameter section 60 and a narrow-diameter section 63. Holder 58 may be made of glass, ceramic or other material capable of being formed to specified dimensions with precise tolerances.

In order to attach holder 58 to the end of fiber 18, the fiber is first prepared as shown in Figure 7. More particularly, prior to insertion of fiber 18 into holder 58, a portion of buffer sheath 61 is removed, exposing a length of optically-conductive core 65. Care is taken when stripping buffer sheath 61 from the fiber not to damage the layer of reflective cladding 67 located on the surface of core 65. After stripping, fiber 18 is inserted into holder 58 so that core 65 extends into the small-diameter bore 63 and sheath 61 extends into the large-diameter bore 60. After fiber 18 has been inserted into holder 58, it may be fastened by epoxy cement to permanently affix the components. To complete the assembly, the end of fiber 18 which protrudes beyond surface 62 of holder 58 may be finished flush with the surface by grinding the assembly or by carefully cleaving the fiber.

Referring to Figure 6, holder 58 (with fiber 18 fastened inside) is mounted within a glass tube 51 to shield the assembly. The front surface, 62, of holder 58 is spaced from the inner surface 142 of planar lens 144, which may be comprised of glass or sapphire, by means of a spacing ring 154. Ring 154 may illustratively be made of radiopaque material so that the catheter tip can be located inside the patient by means of a fluoroscope.

Glass tubing 51 is bent over shoulder 68 of holder 58 to form a constricted end, 65, which holds the probe tip

assembly together. A filler, 66, which may be made of a plastic such as TEFLON (trademark of the DuPont corporation for polytetrafluoroethylene) fills the annular space between catheter body 30 and end 65 of glass tube 51. The outer diameter of the entire assembly from catheter body 30 to glass tube 51 is substantially the same, providing a smooth, uniform surface along the entire length of the catheter as indicated in Figure 6.

Figure 8 shows a schematic diagram of a wire-guided, four-fiber catheter for use with the present invention. The laser system is set up as previously described with the infrared laser 21 constructed in accordance with the above disclosure. A visible helium-neon aiming laser 20 may also be used in line with laser 21 for aiming purposes as discussed with the single fiber catheter. The output of the infrared laser 21 is directed towards a set of four mirrors 60-68 arranged at a 45° angle with respect to the axis of beam 14.

The first mirror, 60, has a 25% reflective surface and directs approximately 1/4 of the energy to focusing lens 70. The second mirror of the set, 62, is a 33% reflector which directs 1/4 of the total energy to focusing lens 72. Mirror 64 is a 50% reflector which directs 1/4 of the total laser output to focusing lens 74. The last mirror in the set, mirror 68, is a 100% reflector which directs the remaining 1/4 of the total energy to focusing lens 78. Mirrors 60-68 and lenses 70-78 are conventional devices.

Focusing lenses 70-78 focus the output energy from IR laser 21 onto four fiber optic connectors ,80-88. Connectors 80-88 are connected, respectively, to tubes 90-96 which are all connected, via a branch connector 102, to catheter 104. Each of tubes 90-96 contains a single optical fiber which transmits 1/4 of the total laser output energy through the catheter body to the catheter tip 108. An additional tube 98 is provided which is connected to branch fitting 102 and to a conventional Luer-Lok connector, 100. This latter tube is connected to a central lumen in catheter body 104 through which flushing solutions may be injected or through which a guide wire may be inserted through the catheter for purposes of guiding the catheter to the surgical area.

At catheter tip 108, the four optical fibers which pass through the catheter are arranged symmetrically so that the beams 110 overlap to illuminate a larger area. Tip 108 also has a hole on the center thereof, through which guidewire 112 can protrude to direct the catheter to the proper location.

Figures 9 and 10 show detailed views of the illustrative four-fiber catheter tip. The four optical fibers 42 and the inner shaft 40 which holds the fibers, are held in a fiber holder 50 which is preferably formed from a radiopaque material such as stainless steel or platinum. Fiber holder 50 is cylindrical and is provided with a central aperture, 54, which communicates with a lumen 34 of approximately the same size that passes through the center of the catheter body

104. Fiber holder 50 is provided with a plurality of longitudinally extending holes 56 which extend through the wall of holder 50 and receive, in a snug fit, the distal ends of the fiber cores 42. The distal face 58 of the combined fiber cores 42 and holder 50 is polished flat to butt flush against optically transparent cap 52.

Cap 52 is cylindrical and has the same outer diameter as catheter body 104 so that the two pieces define a smooth and continuous diameter. Cap 52 may be formed of a transparent substance such as pyrex glass or sapphire and has an enlarged bore 62 extending in from its proximal end. Bore 62 terminates at its end to form internal shoulder 60. A smaller diameter central aperture, 64, is formed in the distal end of cap 52 which aperture may have the same diameter as aperture 54 in fiber holder 50 and lumen 34 in catheter body 104 to provide a smooth and continuous lumen which opens at the distal tip of the catheter. However, the aperture 64 in tip 52 may also be somewhat narrower than aperture 54 and lumen 34 as long as sufficient clearance is provided to accommodate a guidewire without adversely interfering with fluid flow and pressure measurements.

Cap 52 is secured by an epoxy adhesive (placed on its inner surface 62) to the fiber holder 50 and also to the portion of the inner shaft 40 and fibers 42 which are disposed within the proximal end of the cap 52. The distal end of the catheter body 104 is heat shrunk around the inner

shaft 40 and fibers 42 to provide a smooth transition from cap 52 to catheter body 104.

More complete construction details of a four-fiber catheter suitable for use with the illustrative embodiment are given in co-pending U.S. patent application entitled "Wire Guided Laser Catheter", filed on May 22, 1985 by Stephen J. Herman, Laurence A. Roth, Edward L. Sinofsky and Douglas W. Dickinson, Jr.

Figure 11 illustrates the output beam pattern developed by a four-fiber catheter, such as that described above, in which the four fibers are arranged in two diametrically-opposed pairs. The beam pattern from each of the four fiber ends is defined by a cone formed by the ray lines 70 in Figure 11. The beam from each individual fiber 42 is emitted from the distal face of the fiber 42 and enters the distal segment 72 of cap 52 through the face defining the shoulder 60. The beam from each fiber is divergent and, in the illustrative embodiment, may have a half-angle in the range of 6°-16°, depending on the numerical aperture of the fibers which are used to construct the catheter.

The diverging beam from each of the fibers 42 exits from the distal emission face 74 at the end of cap 52. Figures 11A, 11B and 11C illustrate the overall beam pattern (in cross-section) which is formed by the output of the four fibers as seen along image planes 11A, 11B and 11C in Figure 11. At plane 11A, which is located at the emission face 74

of cap 52, the four beams in the illustrative embodiment are still separate. At plane 11B, the diverging beams have spread further and have begun to overlap. At the plane indicated as 11C, the beams have overlapped and define an envelop 73 having an outer diameter which is slightly greater than the outer diameter of the catheter body 104. Preferably, at plane 11C, beams 70 will have overlapped to merge and cover a continuous pattern. Illustratively, such a merger will have occurred within a distance from the distal face 74 of tip 52 which is approximately equal to the outer diameter of catheter 104 (a typical diameter is 1.5 millimeters).

<u>What is Claimed is:</u>

1. A system for the surgical removal of biological material comprising,

a laser energy source operating with an output wavelength in the range of 1.4-2.2 micrometers,

an optical fiber,

means for directing the output of said laser source to the proximal end of said optical fiber, and

means attached to the distal end of the optical fiber for directing laser energy propagating down said fiber to a surgical site.

2. A system for the removal of biological tissue in accordance with Claim 1 wherein said optical fiber comprises a silica fiber purified to reduce the hydroxyl ion content as low as possible.

3. A system for the removal of biological tissue in accordance with Claim 1 wherein said laser source comprises a Holmium-doped Yttrium-Aluminum-Garnet laser.

4. A system for the removal of biological tissue in accordance with Claim 1 wherein said laser source comprises an Erbium-doped Yttrium-Aluminum-Garnet laser.

5. A system for the removal of biological tissue in accordance with Claim 1 wherein said laser source comprises a Holmium-doped Yttrium-Lithium-Fluoride laser.

6. A system for the removal of biological tissue in accordance with Claim 1 wherein said laser source comprises an Erbium-doped Yttrium-Lithium-Fluoride laser.

7. A system for the removal of biological tissue in accordance with Claim 1 wherein said laser source comprises a Thulium-doped Yttrium-Aluminum-Garnet laser.

8. A system for the removal of biological tissue in accordance with Claim 1 wherein said laser source is operated in a pulsed-mode.

9. A system for the removal of biological tissue in accordance with Claim 8 wherein said laser source is operated in a pulsed-mode with a pulse width substantially equal to 1 millisecond.

10. A system for the removal of biological tissue in accordance with Claim 1 further comprising an aiming laser source generating visible light output and means for directing said visible light output through said laser source and said optical fiber to align said laser and said fiber and to visually illuminate said surgical site.

11. A system for the surgical repair of biological material comprising,

a laser energy source operating in a continuous wave mode with an output wavelength in the range of 1.4-2.2 micrometers,

an optical fiber,

means for directing the output of said laser source to the proximal end of said optical fiber, and

means attached to the distal end of the optical fiber for directing laser energy propagating down said fiber to a surgical site.

12. A system for the repair of biological tissue in accordance with Claim 11 wherein said optical fiber comprises a silica fiber purified to reduce the hydroxyl ion content as low as possible.

13. A system for the repair of biological tissue in accordance with Claim 11 wherein said laser source comprises a Holmium-doped Yttrium-Aluminum-Garnet laser.

14. A system for the repair of biological tissue in accordance with Claim 11 wherein said laser source comprises an Erbium-doped Yttrium-Aluminum-Garnet laser.

15. A system for the repair of biological tissue in accordance with Claim 11 wherein said laser source comprises a Holmium-doped Yttrium-Lithium-Fluoride laser.

16. A system for the repair of biological tissue in accordance with Claim 11 wherein said laser source comprises an Erbium-doped Yttrium-Lithium-Fluoride laser.

17. A system for the repair of biological tissue in accordance with Claim 11 wherein said laser source comprises a Thulium-doped Yttrium-Aluminum-Garnet laser.

18. A system for performing surgical operations on biological material comprising,

a laser energy source operating with an output wavelength in the range of 1.4-2.2 micrometers,

a catheter having at least one lumen passing therethrough,

at least one optical fiber comprised of silica passing through said catheter lumen,

a focussing lens for directing the output of said laser source onto the proximal end of said optical fiber, and

a lens attached to the distal end of the optical fiber for directing laser energy propagating down said fiber to a surgical site.

19. A system for performing surgical operations on biological tissue in accordance with Claim 18 further comprising a fiber optic connector affixed to the proximal end of said fiber for holding said fiber.

20. A system for performing surgical operations on biological tissue in accordance with Claim 18 wherein said catheter

has an additional lumen passing therethrough, said additional lumen having an opening at the proximal and distal ends for communicating with said surgical site.

21. A system for performing surgical operations on biological tissue in accordance with Claim 18 wherein said optical fiber comprises a silica fiber purified to reduce the hydroxyl ion content as low as possible.

22. A system for performing surgical operations on biological tissue in accordance with Claim 18 wherein said laser source comprises a Holmium-doped Yttrium-Aluminum-Garnet laser.

23. A system for performing surgical operations on biological tissue in accordance with Claim 18 wherein said laser source comprises an Erbium-doped Yttrium-Aluminum-Garnet laser.

24. A system for performing surgical operations on biological tissue in accordance with Claim 18 wherein said laser source comprises a Holmium-doped Yttrium-Lithium-Fluoride laser.

25. A system for performing surgical operations on biological tissue in accordance with Claim 18 wherein said laser

source comprises an Erbium-doped Yttrium-Lithium-Fluoride laser.

26. A system for performing surgical operations on biological tissue in accordance with Claim 18 wherein said laser source comprises a Thulium-doped Yttrium-Aluminum-Garnet laser.

27. A system for performing surgical operations on biological tissue in accordance with Claim 18 wherein said laser source is operated in a pulsed-mode.

28. A system for performing surgical operations on biological tissue in accordance with Claim 27 wherein said laser source is operated in a pulsed-mode with a pulse width substantially equal to 1 millisecond.

29. A system for performing surgical operations on biological tissue in accordance with Claim 18 further comprising an aiming laser source generating visible light output and means for directing said visible light output through said laser source and said optical fiber to align said laser and said fiber and to visually illuminate said surgical site.

30. A system for the surgical repair of biological material comprising,

a laser energy source operating in a continuous wave mode and generating an output beam with a wavelength in the range of 1.4-2.2 micrometers,

a plurality of optical fibers,

a plurality of partially reflective mirrors arranged in series along the axis of said output beam for directing a portion of the output of said laser source to the proximal ends of said optical fibers, and

a plurality of focussing lenses positioned between said mirrors and the proximal ends of said fibers for focussing portions of said laser output to the proximal ends of said fibers, and

means attached to the distal end of the optical fiber for directing laser energy propagating down said fibers to a surgical site, said directing means holding said fibers in a fixed position relative to one another so that optical beams emanating from the distal ends of said fibers overlap to cover an area at least equal to the diameter of said catheter.

31. A system for the repair of biological tissue in accordance with Claim 30 wherein at least some of said optical fibers comprise silica fibers purified to reduce the hydroxyl ion content as low as possible.

32. A system for the repair of biological tissue in accordance with Claim 30 wherein said laser source comprises a Holmium-doped Yttrium-Aluminum-Garnet laser.

33. A system for the repair of biological tissue in accordance with Claim 30 wherein said laser source comprises an Erbium-doped Yttrium-Aluminum-Garnet laser.

34. A system for the repair of biological tissue in accordance with Claim 30 wherein said laser source comprises a Holmium-doped Yttrium-Lithium-Fluoride laser.

35. A system for the repair of biological tissue in accordance with Claim 30 wherein said laser source comprises an Erbium-doped Yttrium-Lithium-Fluoride laser.

36. A system for the repair of biological tissue in accordance with Claim 30 wherein said laser source comprises a Thulium-doped Yttrium-Aluminum-Garnet laser.

37. A system for the repair of biological tissue in accordance with Claim 30 further comprising a fiber optic connector affixed to the proximal ends of each of said fibers for holding said fibers.

38. A system for the repair of biological tissue in accordance with Claim 30 wherein said catheter has an additional lumen passing therethrough, said additional lumen having an opening at the proximal and distal ends for communicating with said surgical site.

39. A system for the repair of biological tissue in accordance with Claim 30 wherein said laser source is operated in a low-power continuous mode.

40. A system for performing surgical operations on biological tissue in accordance with Claim 30 further comprising an aiming laser source generating visible light output and means for directing said visible light output through said laser source and said optical fiber to align said laser and said fiber and to visually illuminate said surgical site.

41. A method for the surgical removal of biological material comprising the steps of:

A. operating a laser energy source to produce an output beam with a wavelength in the range of 1.4-2.2 micrometers,

B. directing the output of said laser source to the proximal end of an optical fiber, and

C. directing laser energy propagating down said fiber to a surgical site.

42. A method for the removal of biological tissue in accordance with Claim 41 wherein step A comprises the steps of operating said laser source in a pulsed-mode with a pulse width substantially equal to 1 millisecond.

43. A method for the surgical repair of biological material comprising the steps of:

A. operating a laser energy source in a continuous wave mode with an output wavelength in the range of 1.4-2.2 micrometers,

B. directing the output of said laser source to the proximal end of said optical fiber, and

C. directing laser energy propagating down said fiber to a surgical site.

INFRARED LASER CATHETER SYSTEM

ABSTRACT OF THE DISCLOSURE

Laser energy produced by a laser operating in the mid-infrared region (approximately 2 micrometers) is delivered by an optical fiber in a catheter to a surgical site for biological tissue removal and repair. Disclosed laser sources which have an output wavelength in this region include: Holmium-doped Yttrium Aluminum Garnet (Ho:YAG), Holmium-doped Yttrium Lithium Fluoride (Ho:YLF), Erbium-doped YAG, Erbium-doped YLF and Thulium-doped YAG. For tissue removal, the lasers are operated with relatively long pulses at energy levels of approximately 1 joule per pulse. For tissue repair, the lasers are operated in a continuous wave mode at low power. Laser output energy is applied to a silica-based optical fiber which has been specially purified to reduce the hydroxyl-ion concentration to a low level. The catheter may be comprised of a single optical fiber or a plurality of optical fibers arranged to give overlapping output patterns for large area coverage.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Edward L. Sinofsky
Serial No.: --
Filed: Herewith
For: INFRARED LASER CATHETER SYSTEM

Examiner: David Shay
Art Unit: 3309

Hon. Commissioner of Patents
and Trademarks
Waskhington D.C. 20231
Attn: Official Draftsman

LETTER TO OFFICIAL DRAFTSMAN

Sir:

Approval is respectfully requested to correct certain errors in the reference numerals in Figures 8, 9, 10, and 11. The proposed corrections are shown in red on the attached photocopies.

In particular, in Figure 8, reference numerals 60-68 have been changed to 160, 162, 164 and 168 respectively. In Figure 9, the reference numeral 62 has been changed to reference numeral 262, reference numeral 58 has been changed to reference numeral 158, and reference numeral 64 has been changed to reference numeral 264. A corresponding change was made in

Figure 10. In Figure 11, reference numeral 60 was changed to reference numeral 260.

Respectfully submitted,

NUTTER, MCCLENNEN & FISH, LLP

By _____
Thomas J. Engellenner
Reg. No. 28,711

One International Place
Boston, MA 02110
617-439-2948
November 30, 1998

8505L.270260

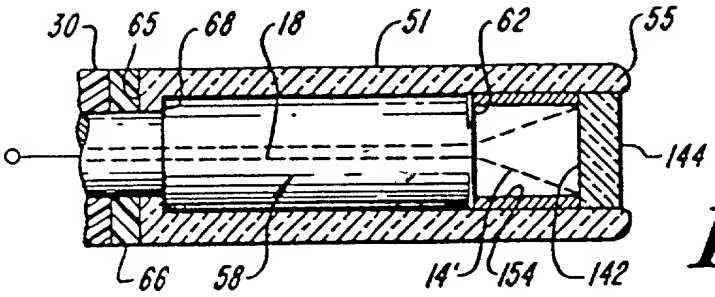
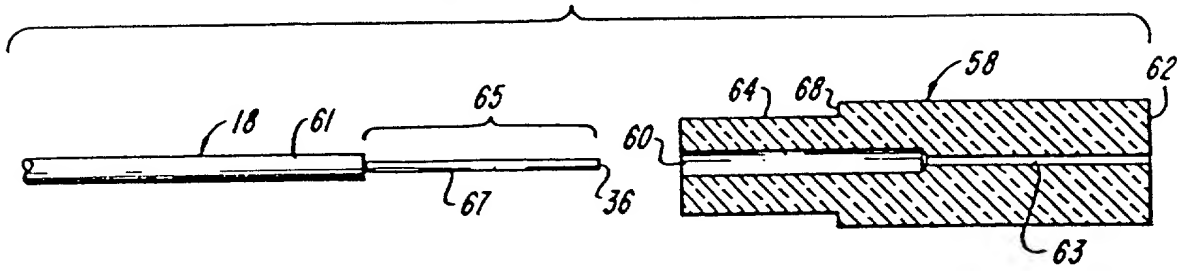


FIG. 6

FIG. 7



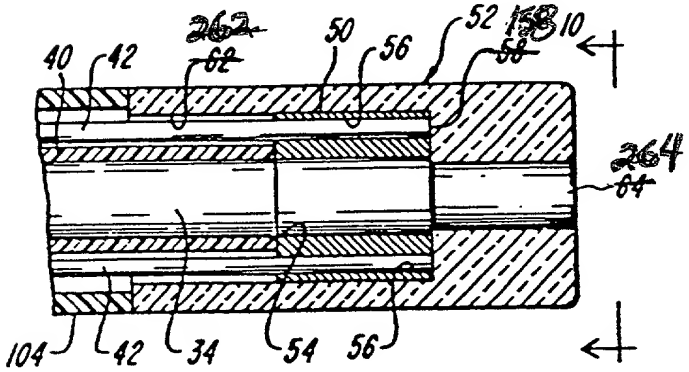


FIG. 9

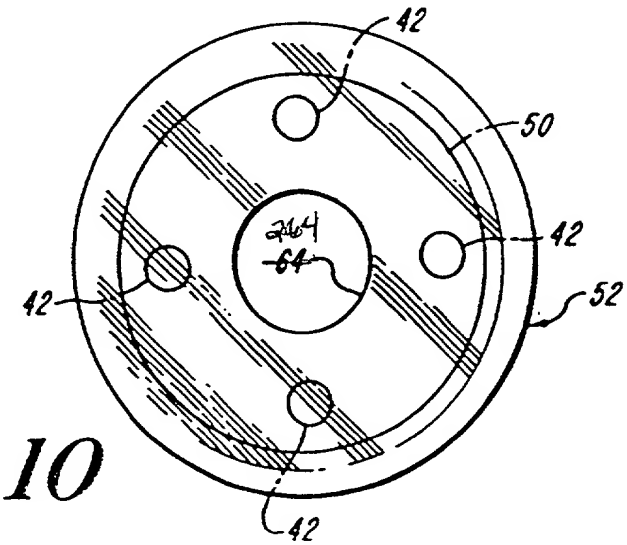


FIG. 10

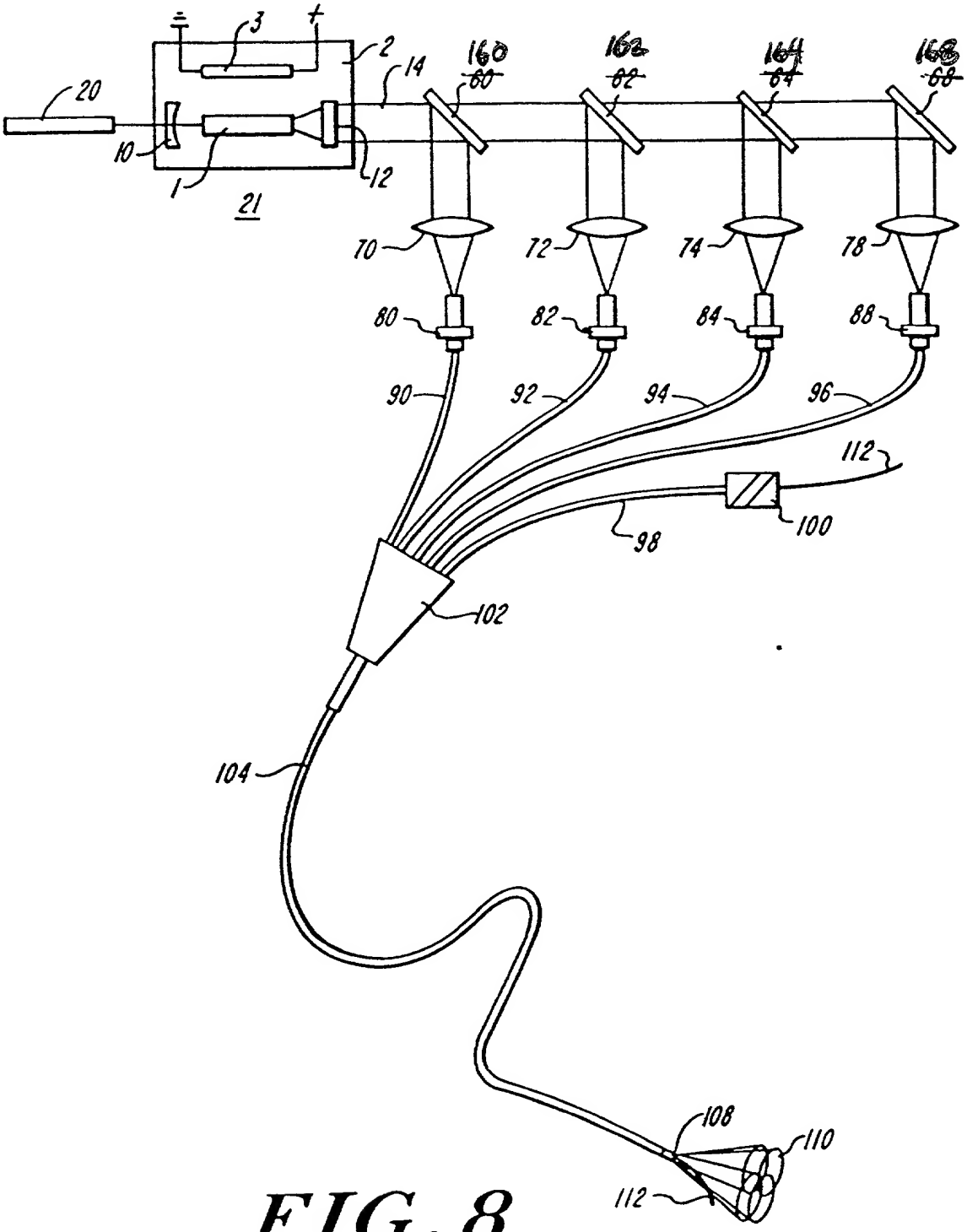

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FIG. 8

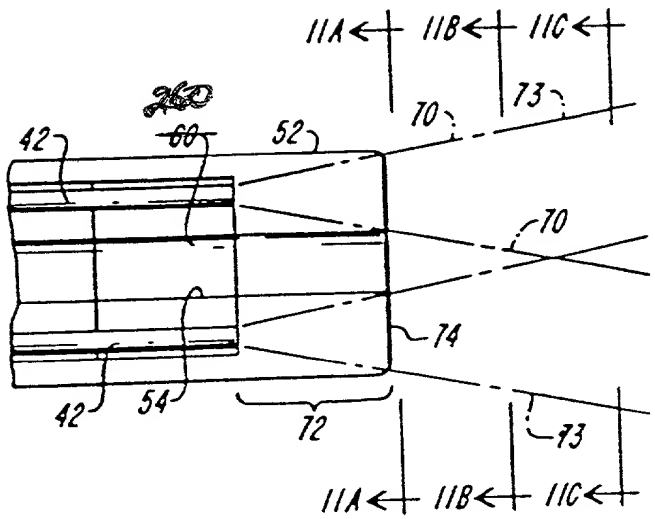


FIG. 11

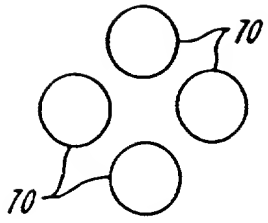


FIG. 11A

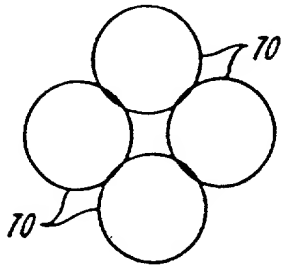


FIG. 11B

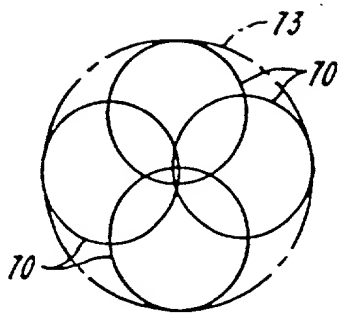
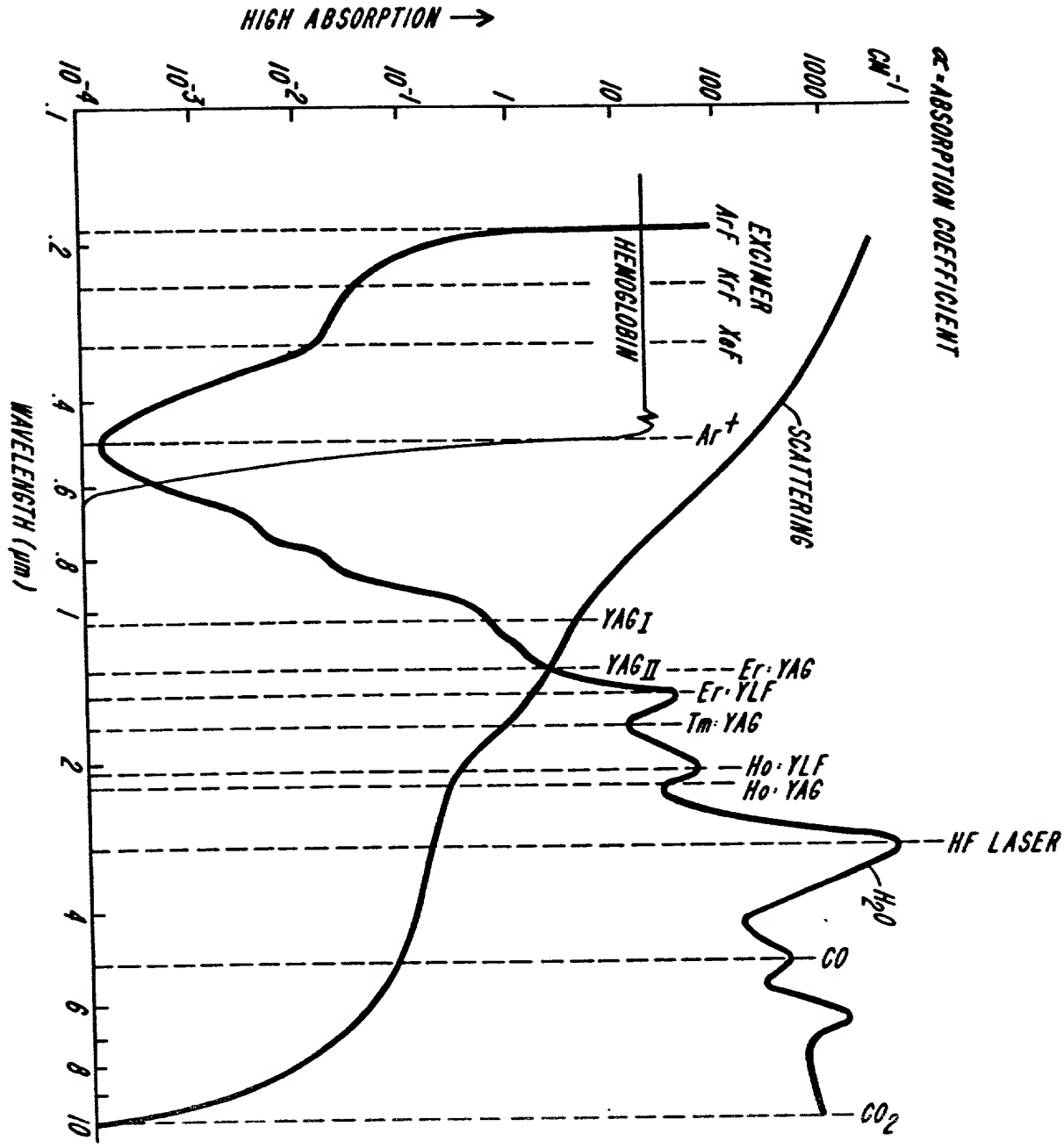


FIG. 11C


HIGH ABSORPTION →
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Ar^+
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FIG. 1

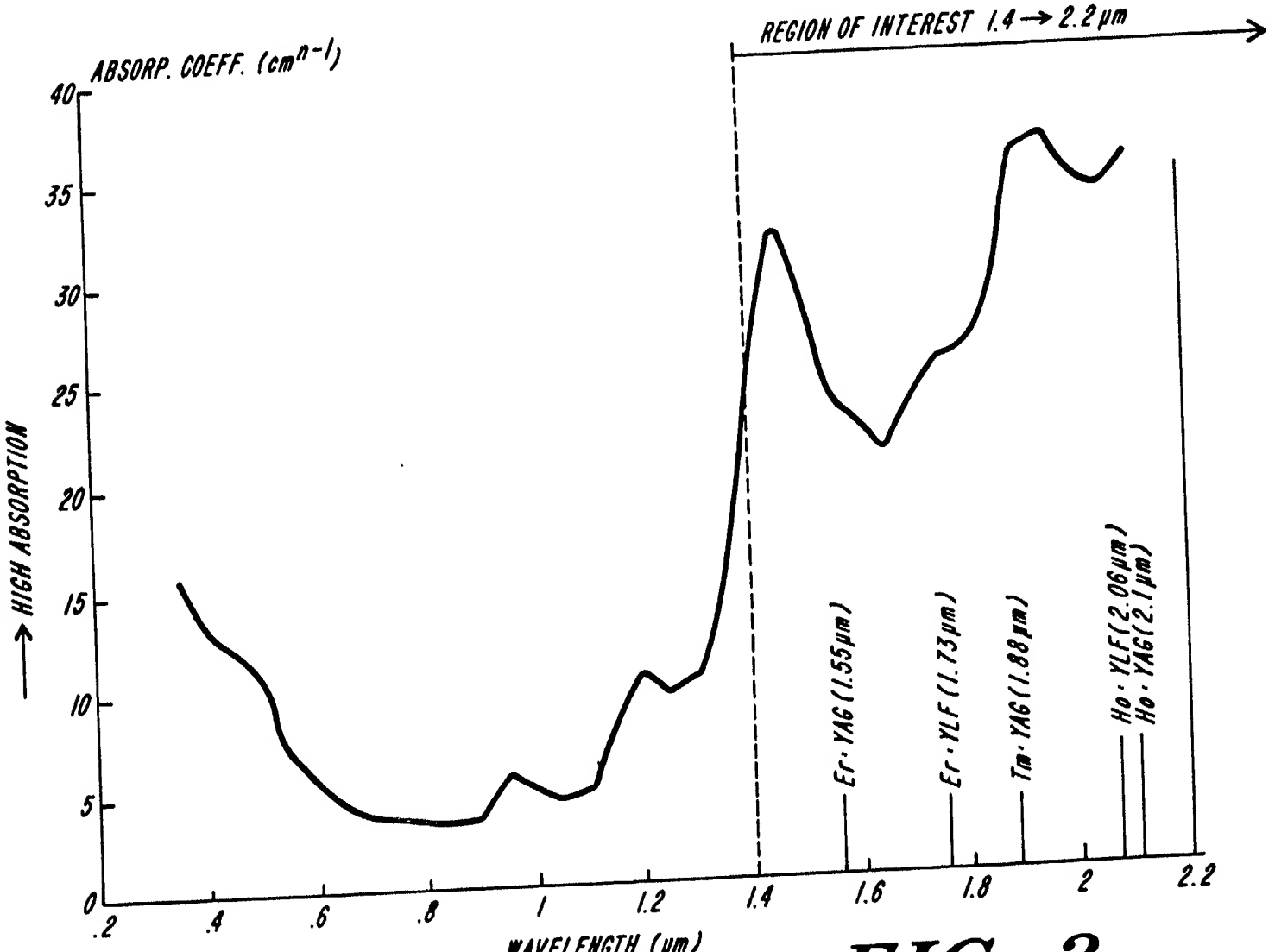

FIG. 2

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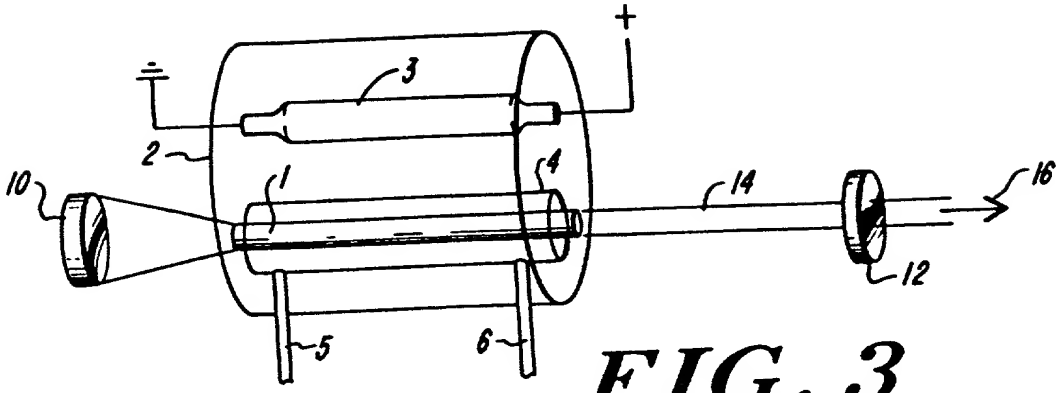

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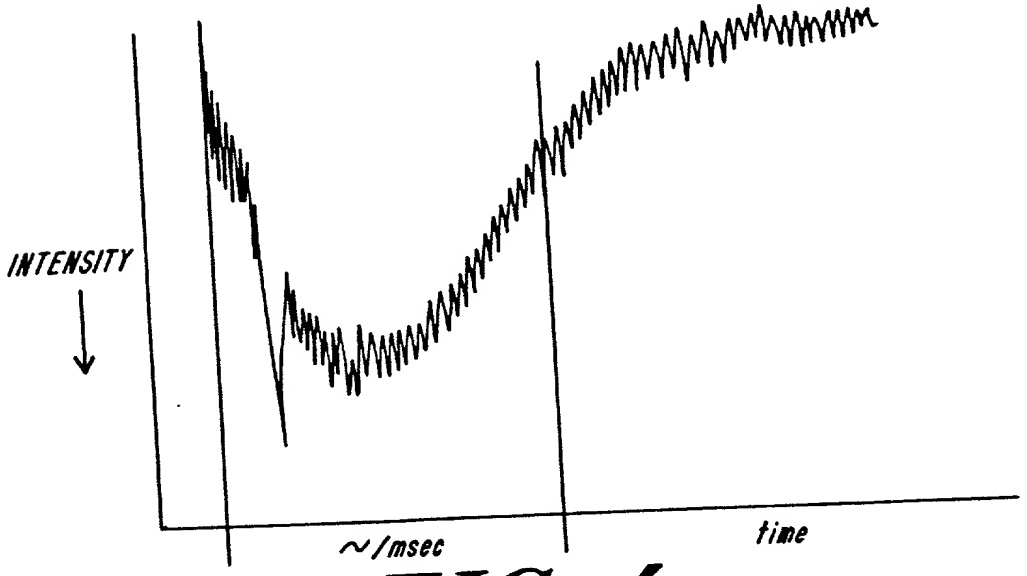

FIG. 4

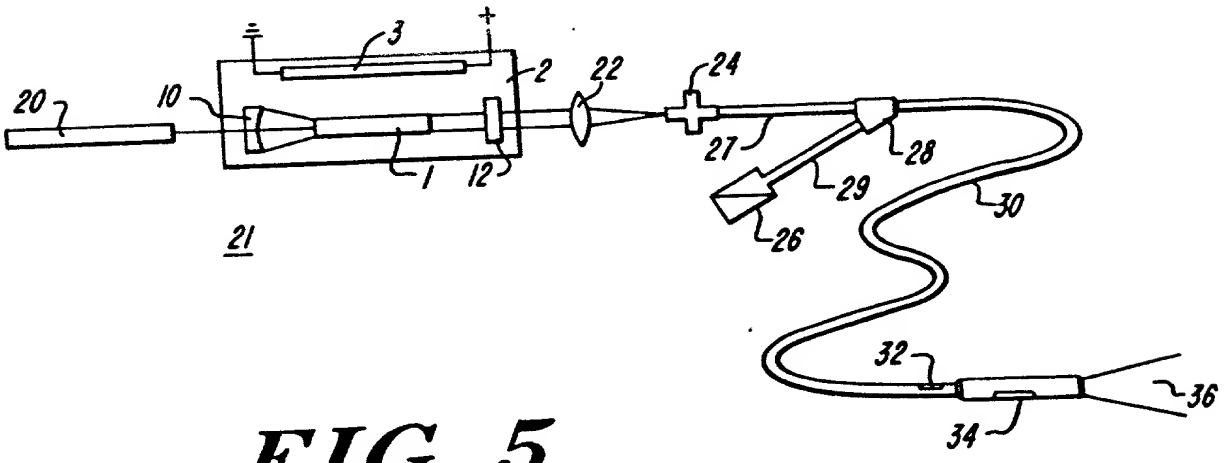

FIG. 5

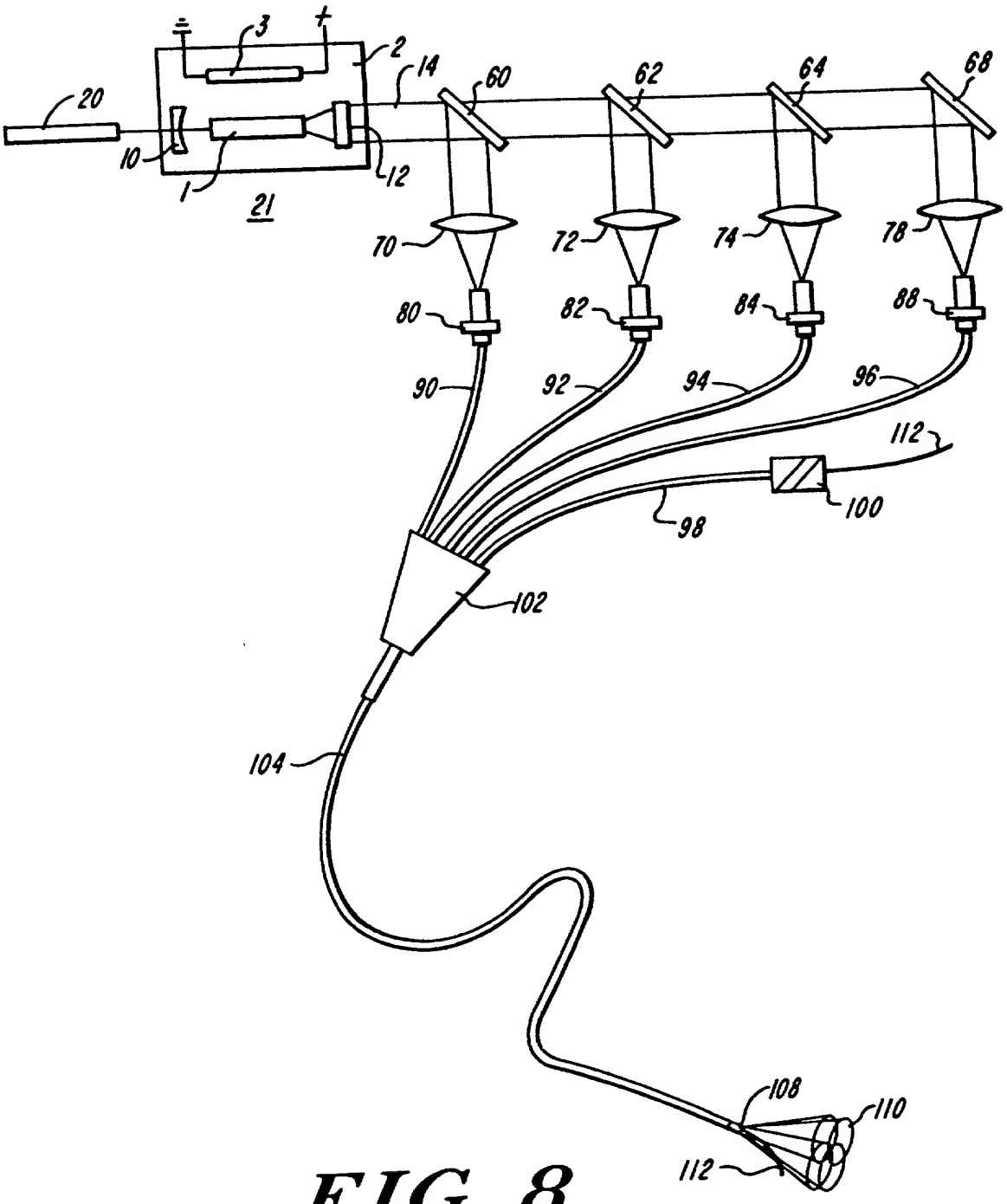
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FIG. 8

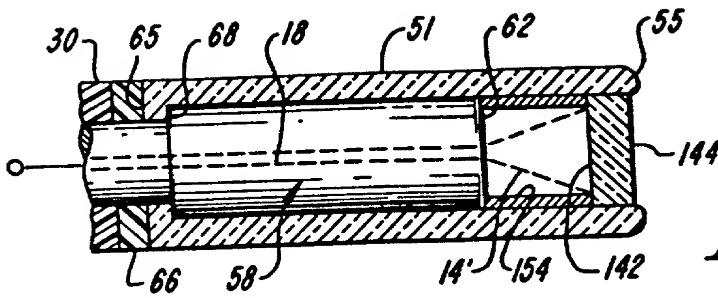
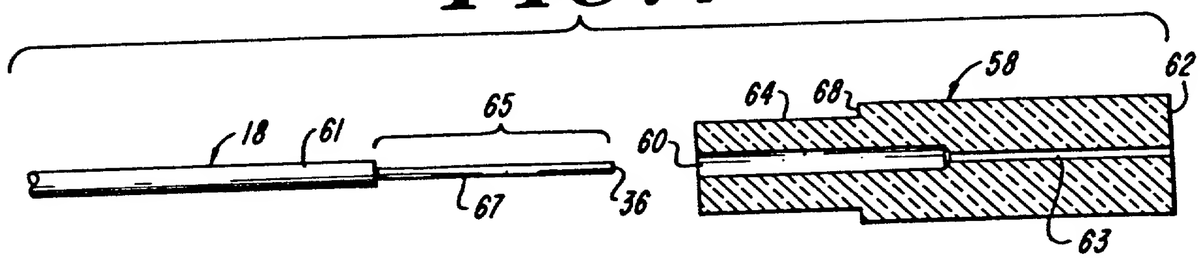


FIG. 6

FIG. 7



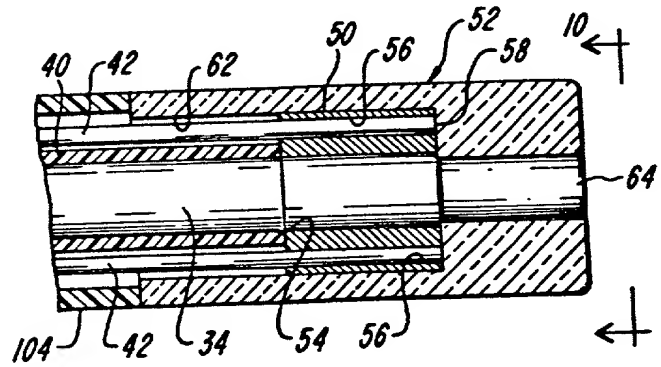


FIG. 9

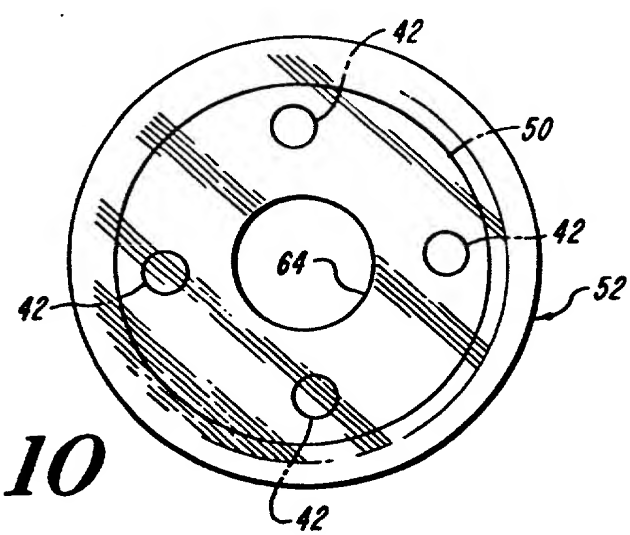


FIG. 10

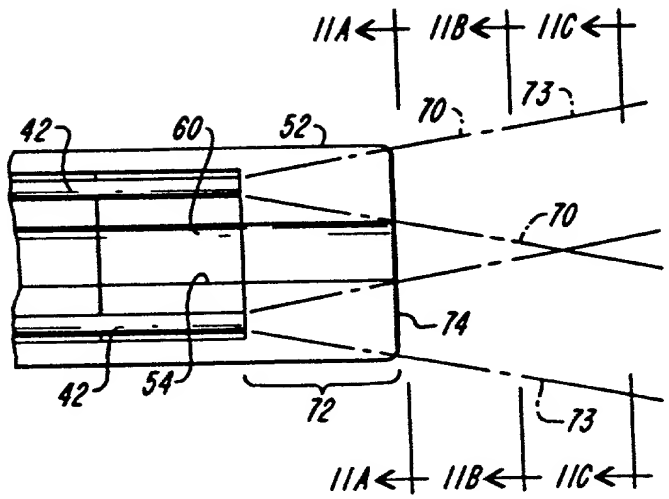


FIG. 11

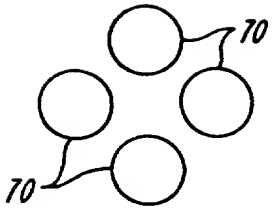


FIG. 11A

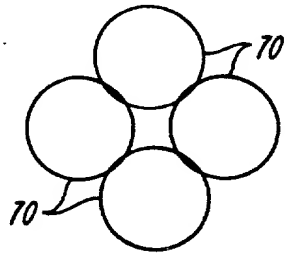


FIG. 11B

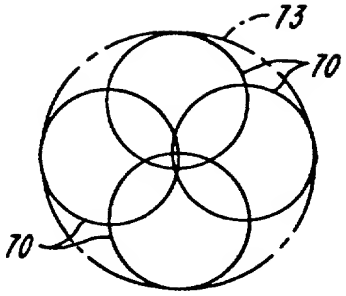


FIG. 11C

Docket No. 2B410/718

DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled INFRARED LASER CATHETER SYSTEM, the specification of which

(check one) ☒ is attached hereto.

☐ was filed on _____

Application Serial No. _____ as

and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

(Number)	(Country)	(Day/Month/Year Filed)	Priority Claimed
NONE			
(Number)	(Country)	(Day/Month/Year Filed)	Yes No
(Number)	(Country)	(Day/Month/Year Filed)	Yes No
(Number)	(Country)	(Day/Month/Year Filed)	Yes No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.)	(Filing Date)	(Status—patented, pending, abandoned)
NONE		
(Application Serial No.)	(Filing Date)	(Status—patented, pending, abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

David Wolf, Reg. No. 17,528;
George L. Greenfield, Reg. No. 17,756;
Stanley Sacks, Reg. No. 19,900;
Louis Orenbuch, Reg. No. 17,318;
David M. Driscoll, Reg. No. 25,075;
Arthur Z. Bookstein, Reg. No. 22,958;
Edward F. Perlman, Reg. No. 28,105;
Alfred H. Rosen, Reg. No. 16,031;
John L. Welch, Reg. No. 28,129;
Paul Kudirka, Reg. No. 26,931;
Susan Haddad Hage, Reg. No. 29,64
Lawrence M. Green, Reg. No. 29,38
Edward R. Schwartz, Reg. No. 31,1
Therese A. Hendricks, Reg. No. 30,38

Address all telephone calls to Paul E. Kudirka at telephone no. (617) 426-6131 (617) 426-6131

Address all correspondence to Paul E. Kudirka
c/o Wolf, Greenfield & Sacks, P.C.
201 Devonshire Street
Boston, MA 02110

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Inventor's signature X Edward Lawrence Sinofsky Date X 7-29 85

Full name of sole or first inventor Edward Lawrence Sinofsky

Citizenship United States

Residence 5 Washington Street, Apt. A8, Reading, MA 01867

Post Office Address same as above

Second Inventor's signature _____ Date _____

Full name of second joint inventor, if any _____

Citizenship _____

Residence _____

Post Office Address _____

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Edward L. Sinofsky

Serial No.: 08/411,581 **Examiner:** D. Shay

Filed: March 29, 1995 **Group Art Unit:** 3311

Title: INFRARED LASER CATHETER SYSTEM

Docket No.: ROE-040C4 (formerly BO410/7228)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on the date set forth below.

11 October 1996 By _____
Date of Signature and of Mail Deposit — Thomas J. Engellenner (Reg. No. 28,711)

Assistant Commissioner for Patents
Washington, D.C. 20231

REVOCATION OF PRIOR POWERS OF ATTORNEY AND APPOINTMENT OF NEW POWER OF ATTORNEY

Dear Sir:

Edward L. Sinofsky, the Applicant and Owner of the entire right, title and interest in the above-identified patent application, hereby revokes all previous Powers of Attorney heretofore granted with respect to that application, and parent applications, Serial Nos. 08/049,147, filed April 19, 1993, which is a divisional of 07/568,348, filed August 15, 1990, which is a continuation of 07/257,760, filed October 14, 1988, now U.S. Patent No. 4,950,226, which is a continuation of 07/014,990, filed February 1, 1987, now abandoned, which is a continuation of 06/761,188, filed July 31, 1985, now abandoned, and appoints the below listed attorneys with full power of substitution and revocation to

prosecute this application and to transact all business in the Patent Office connected therewith:

John A. Lahive, Jr.	Reg. No. 19,788	John V. Bianco	Reg. No. 36,748
W. Hugo Liepmann	Reg. No. 20,407	Jeremiah Lynch	Reg. No. 17,425
James E. Cockfield	Reg. No. 19,162	Amy E. Mandragouras	Reg. No. 36,207
Thomas V. Smurzynski	Reg. No. 24,798	Elizabeth A. Hanley	Reg. No. 33,505
Ralph A. Loren	Reg. No. 29,325	Anthony A. Laurentano	Reg. No. 38,220
Thomas J. Engellenner	Reg. No. 28,711	Jane E. Remillard	Reg. No. 38,872
Giulio A. DeConti, Jr.	Reg. No. 31,503	Mark A. Kurisko	Reg. No. 38,944
Ann Lamport Hammitte	Reg. No. 34,858	Beth E. Arnold	Reg. No. 35,430
Paul Louis Myers	Reg. No. 35,965	Jean M. Silveri	Reg. No. 39,030
Michael I. Falkoff	Reg. No. 30,833	Matthew P. Vincent	Reg. No. 36,709

all of Lahive & Cockfield, 60 State Street, Boston, Massachusetts 02109, United States of America, and

send correspondence to:

Thomas J. Engellenner, Esq.
LAHIVE & COCKFIELD
60 State Street
Boston, MA 02109
(617) 227-7400

Edward L. Sinofsky

EDWARD L. SINOFSKY

Dated: 10/11/96

09201072 - 411581